

Remarks

Information Disclosure Statement

The Examiner did not consider one of the references (Wu) listed on the Form PTO-1449 filed June 26, 2006. A copy of Wu and a new Form PTO-1449 listing Wu accompany this paper. Please consider this reference and return the initialed PTO-1449 with the next Office Action.

Rejection of Claims 10 and 12-19 Under 35 U.S.C. § 112 ¶ 2

Claims 10 and 12-19 stand rejected under 35 U.S.C. § 112 ¶ 2. The Final Office Action contends it is not clear whether the term “reducing” applies to “quiescent stages of cell death” or “eminent [sic] cell death as a result of diverse activating stimuli.” Final Office Action at page 4 ¶ 1. Applicants respectfully traverse the rejection.

The second paragraph of 35 U.S.C. § 112 states that:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims must be read in light of the specification. *See In re Cohn*, 438 F.2d 989, 993, 58 C.C.P.A. 996, 1001 (C.C.P.A. 1971): “No claim may be read apart from and independent of the supporting disclosure on which it is based.” The specification is directed to treatment of neurodegenerative disorders, stroke, and trauma; *i.e.*, conditions in which neurons die in response to a specific stimulus. Thus, when read in light of the supporting disclosure, the term “reducing” is directed towards the cell death which is associated with a neurological disorder.

It is well settled that a claim must “reasonably apprise those skilled in the art both of the utilization and scope of the invention.” *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136, 118 U.S.P.Q. 122, 130 (2d Cir. 1958), *cert. denied*, 358 U.S. 884 (1958).

Claims 10 and 12-19 meet this standard and are therefore definite. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 10 and 12-19 Under 35 U.S.C. § 112 ¶ 1

The Final Office Action maintains the rejection of claims 10 and 12-19 under 35 U.S.C. § 112 ¶ 1 as not enabled. Applicants respectfully traverse the rejection.

The enablement requirement of 35 U.S.C. § 112, first paragraph states that a patent specification must teach a person skilled in the relevant art how to make and use the invention claimed. The proper standard for determining whether the present specification meets the enablement requirement is whether any experimentation which may be needed to practice the methods of claims 10 and 12-19 is undue or unreasonable. *In re Wands*, 858 F.2d 731, 736-37, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

The claims are directed to a method of reducing neuronal cell death in a mammal. The method comprises administering to the mammal a nucleic acid molecule comprising a coding sequence for a neuronal marker (NM) protein selected from a recited group of proteins.¹ The U.S. Patent and Trademark Office has the initial burden to establish a reasonable basis to question the specification's enablement of the claims. *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). To make a *prima facie* case of non-enablement using this standard, an Examiner must properly construe the claims and must weigh all the evidence

¹ The Final Office Action continues to misconstrue the scope of claims 10 and 12-19. The Final Office Action states: “the method claims 10, 12-19 are interpreted as being drawn [to] non-viral therapeutic preventions.” Final Office Action at page 6 ¶ 1. Although the claims encompass “non-viral therapeutic preventions,” they are not limited either to preventing neuronal cell death or to use of non-viral methods of administering the recited nucleic acid molecule to the mammal.

and establish a reasonable basis to question the enablement provided in the specification for the claimed invention. M.P.E.P. §§ 2164.04 and 2164.05, 8th ed., August, 2005.

With the response filed June 26, 2006 Applicants provided thirty-nine references which attest to the ability of those skilled in the art in July 2002 to transfer and express exogenous genes effectively in neurons *in vivo*. The Final Office Action dismisses this evidence by focusing on aspects of the references which are irrelevant to the patent law. For example, the Final Office Action points out that Hecker² used “optimized formulations” to deliver plasmid DNA to target cells. Final Office Action at page 6 last ¶. “Optimization” is not undue experimentation; rather, the standard for whether a claim is enabled is whether any experimentation which must be carried out is undue. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). However, this does not mean that no experimentation at all is permitted. *See Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (Bd. Pat. App. Interf. 1982) (“The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.”).

The Final Office Action notes that those skilled in the art at the time this application was filed were concerned with “issues such as efficient-non toxic vectors, safe and efficient gene transfer, targeting of specific cells for treatment of specific type of disease and stability of expression.” *Id.*, sentence bridging pages 7 and 8. Each of the thirty-nine references cited in the June 26, 2006 response demonstrates that those skilled in the art were well equipped to address these issues and had a variety of tools available with which to successfully deliver to a target cell a nucleic acid molecule encoding a desired protein. The law is clear that the specification need

² Hecker *et al.*, “Nonviral gene delivery to the lateral ventricles in rat brain: initial evidence for widespread distribution and expression in the central nervous system,” *Mol. Ther.* 3, 375-84, March 2001 (abstract).

not teach what is well known in the art. *Genentech Inc. v. Novo Nordisk A/S*, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997).

All the evidence of record must be considered in its entirety. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). When correctly analyzed, the weight of evidence of record in this application favors a finding of enablement of claims 10 and 12-19. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

BANNER & WITCOFF, LTD.

/Lisa M. Hemmendinger/

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By:

Lisa M. Hemmendinger
Registration No. 42,653

Customer No. 22907